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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,121	10/20/2000	Jeffrey Schlom	701319	7805
45733 7590 07/11/2007 LEYDIG, VOIT & MAYER, LTD. TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731			EXAMINER YAEN, CHRISTOPHER H	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 07/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/693,121

Applicant(s)

SCHLOM ET AL.

Examiner

Christopher H. Yaen

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17,20,22,25-31,34 and 36-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17,20,22,25-31,34 and 36-42 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

**Re: Schlom *et al***

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/23/2007 has been entered.

The amendment filed 4/23/2007 is acknowledged and entered into the record. Accordingly, claims 1-16, 18-19, 21, 23-24, 32-33, and 35 are canceled without prejudice or disclaimer, and claims 37-42 are newly added.

Claims 17, 20, 22, 25-31, 34, and 36-42 are pending and examined on the merits. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections Maintained - 35 USC § 102***

The rejection of claims 17, 25-26, 28 and now claims 37-42 under 35 USC § 102(e) as being anticipated by Spitler *et al* (US Patent 5,925,362) is maintained for the reasons of record. Applicant argues that the recited reference does not anticipate the instantly claimed invention because the inventors work pre-dates the earliest possible filing date of Spitler *et al* (i.e. 8/11/1993). Applicant also points to the declaration filed

under 37 CFR § 1.131 by the inventors Jeffery Schlom and Dennis Panicali on 12/01/2005 (see specifically page 2 paragraph 5) which indicates that the inventors work was accomplished prior the earliest effective filing date of the instant invention. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The declaration filed under 37 CFR 1.131 on 12/01/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Spitler *et al* reference. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Spitler *et al* reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). In the instant case, the claims of the instant invention are drawn to a method of generating a cytotoxic T-cell response to PSA comprising the administration of first pox virus vector encoding a PSA antigen or a T-cell eliciting epitope thereof and subsequently administering an additional dose of the PSA antigen or T-cell eliciting epitope thereof.

The declaration presented on 12/1/2005 details the generation of a vaccinia virus expressing PSA (see exhibit "A" of the declaration) as well as brief outline which utilizes the vaccinia virus expressing the PSA. This declaration, however, is not commensurate in scope to the claimed invention. First, the declaration does not provide for any

indication or conception of multiple administrations of the vector expressing the PSA antigen of the T-cell eliciting epitope thereof. Secondly, the evidence provided to support the assertions that the invention was conceived prior to 8/11/2003 include constructions of the vector expressing the PSA (see exhibit "A") and brief outlines of using the vector, including "Generation and analysis of virus stock", "Product Manufacture", "Testing/Final reports", and "Master File Preparation". None of the evidence provided, details the conception of administering the PSA encoding pox viral vectors or a method of multiple administrations of pox viral vectors encoding PSA T-cell eliciting epitopes as claimed. The declaration appears to document the production of vectors comprising the gene encoding PSA. As such, the declaration is not commensurate in scope to the claimed invention.

Therefore, the rejection of claims under 35 USC 102(e) as being anticipated is maintained for the reasons of record.

***Claim Rejections Maintained - 35 USC § 103***

The rejection of claims 17,20,22,25-31,34-36, and now newly added claims 37-42 under 35 USC § 103(a) as being obvious over Spitler *et al* in view of Fields and Hodge *et al* is maintained for the reasons of record. Applicant's arguments are substantially similar to those presented for the 102(e) rejection above. Therefore, applicant's arguments have been carefully considered and are not deemed persuasive to overcome the rejection of record. The rejection of the claims under 35 USC 103(a) is maintained for the reasons of record.

***NEW CLAIM OBJECTIONS***

Claims 17 and its dependents are objected to because of the following informalities: claim 17 recites in line 8 the phrase "and then administering the first pox virus vector". The claim is unclear because the method already recited an administration of a "first pox virus vector" in line 3 of claim 17. Appropriate correction and or clarification is required.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher Yaen/  
Primary Examiner  
Art Unit 1643  
July 8, 2007